

**Testimony of Peter Lurie, MD, MPH
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on Mad Cow Disease Surveillance
before a Joint Meeting of the
United States House of Representatives
Committee on Government Reform and Committee on Agriculture
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Any consideration of the prevention of bovine spongiform encephalopathy (BSE) in the United States must begin by acknowledging that the two most important firewalls against the disease are a) the ban on the importation of ruminants from countries with cases of BSE; and b) the ban on the feeding of certain animal parts to ruminants (the feed ban). Unfortunately neither firewall has been adequately in place. It has become clear that, even while the U.S. Department of Agriculture (USDA) claimed to be considering whether or not to allow processed beef into the United States from Canada, where two cattle appear to have acquired BSE, the agency was routinely permitting the importation of such beef.¹ And while the Food and Drug Administration (FDA) claimed in January that it would be eliminating such unjustified exemptions to the ruminant feed ban as chicken litter (spilled feed, bedding, feathers and fecal matter from poultry) and plate waste (uneaten meat and other meat scraps rendered into animal feed) in the form of a soon-to-be-issued Interim Final Rule,² consideration of these exemptions has now been relegated to the status of an Advance Notice of Proposed Rulemaking³ and thus is unlikely to be finalized for months, if not years.

The USDA's Expanded Surveillance Program⁴ must be seen in this context. The purpose of this plan and its predecessor is to quantify the extent of any BSE outbreak, not to prevent disease *per se* (as witnessed by the now-abandoned practice of allowing most cattle with pending BSE tests to enter the food supply). Of course, quantifying any outbreak provides the basic raw data for later efforts to prevent further disease. Critical elements of any surveillance program include a) proper communication of its limits to the public; and b) consistent implementation of the program as designed. In both respects, USDA's efforts to date have been lacking. In particular,

1. The previous surveillance system was never able to detect BSE if it was present in only one in a million adult cattle, as the USDA has claimed; the Expanded Surveillance Program will be similarly unable to detect BSE if it is present in one in 10 million adult cattle, as the USDA now claims.
2. The removal of non-ambulatory ("downer") cattle from the human food supply will not greatly reduce the risk to humans.
3. The previous surveillance system was characterized by inconsistent sampling of downer cattle or the still-more-risky cattle with central nervous system (CNS) disease, and appears not to have obtained adequate geographical representation.

The USDA has claimed on its surveillance website⁵ that the agency's previous surveillance system "should allow detection of a case if BSE truly exists at a level of one or more cases per million in the adult cattle population," a claim reiterated repeatedly by USDA officials in the aftermath of the Washington BSE case. Now, with expanded surveillance, the agency claims that "Assuming all the BSE positive cattle are part of the high risk population," this new "level of sampling would allow us to detect BSE at a rate of 1 positive in 10 million adult cattle at a 95 percent confidence level."⁴ Both claims rest on a false assumption which has been rebutted by testing data from Europe, some of which actually appear on the USDA website.

It is certainly true that the risk of BSE is higher in downer than in non-downer cattle; this has been the justification for the USDA BSE surveillance program's particular focus to date on downer cattle. But the USDA has gone further and assumed that *all* BSE infections that might exist in the United States would occur in the downer/high-risk population. In fact, data from the European Commission demonstrate that 287 normal-appearing cattle tested positive for BSE in Europe in 2002.⁶ While the fraction of normal-appearing cattle that tested positive for BSE in Europe was predictably lower than that fraction in the downer population (the same should be true domestically), there are approximately 100 times more normal-appearing adult animals than there are downer/high-risk animals in the United States (446,000 downer/high-risk animals among 45 million adult cattle).⁴ Thus, unless the risk of BSE among downer/high-risk animals is *much* higher than that among normal-appearing animals, there can actually be substantially more BSE risk among normal-appearing animals than among downer/high-risk animals. By analogy, a higher fraction of drivers of red sports cars may be at risk of incurring or causing injury than drivers of other cars, but most injuries do not involve red sports car drivers.

The attached figure illustrates this point. Based on the USDA's data on the number of animals in the downer/high-risk population, we have constructed a curve that demonstrates how the fraction of total BSE risk that exists among downer/high-risk cattle varies according to how many times more risky such cattle are than normal-appearing cattle. If, for example, downer/high-risk cattle are 500 times more at risk for BSE than normal-appearing cattle, 83% of all BSE cases would be expected among downer/high-risk cattle and a policy of excluding all downer/high-risk cattle would have a significant impact in reducing BSE risk to humans. On the other hand, if downers and other high-risk animals were only five times more risky, only 5% of the risk would be among those animals. Actual testing data from Europe,⁶ not adjusted for animal age, suggest that we are closer to the latter than the former: cattle populations analogous to what are termed downer cattle in the United States have a BSE prevalence 31 times higher than non-downer cattle.* If this ratio is applied (rather than the USDA's assumption that there is no risk whatsoever among normal-appearing animals and that the ratio is therefore infinite), we can see from the figure (indicated by the arrow) that only an estimated 24% of the total U.S. risk occurs among downer/high-risk animals, with the remaining 76% occurring among the normal-appearing cattle that, until recently, were not being tested in the United States.

* Due to lack of specific-enough data, this testimony assumes that the prevalence of BSE in downer animals is about equal to that in other high-risk animals.

This observation has two main implications. First, the USDA claim that testing to date could detect BSE at a level of one in a million adult cattle was false as is the analogous claim that the Expanded Surveillance Plan could detect BSE at a level of one in 10 million adult cattle, because both claims rest on the same false assumption. In order to truly be able to detect the one in 10 million risk, some mix of downer/high-risk and significantly more testing of normal-appearing animals would be necessary.

The numbers are daunting. If the USDA-proposed 20,000 tests over approximately one year on normal-appearing cattle are all negative, one can still only assume (at the 95% confidence level standard in such calculations) that BSE does not exist at a prevalence exceeding 150 per million. If we apply that proportion to the 12% of the 35.7 million cattle slaughtered annually in the United States⁷ that are over the age of 20 months⁵ (the age above which all BSE cases worldwide have been detected), that would still mean as many as 643 infected cattle of that age could proceed to market that year without a single case being detected.

To completely eliminate BSE risk would require the testing of all cattle (or at least those over 20-30 months). Testing as many downer/high-risk animals as possible, combined with testing a large number of older normal-appearing cattle, as the USDA is currently proposing, will generate a more informative estimate of the extent of the disease. This approach is consistent with that recommended by the USDA's international subcommittee,⁸ the U.S. Food and Drug Administration's (FDA's) Transmissible Spongiform Encephalopathy Advisory Committee⁹ and an editorial in the *New England Journal of Medicine*.¹⁰

The second implication is that although removing downer/high-risk cattle from human consumption was appropriate because these animals are more risky, the overall risk to the public was only slightly reduced by this measure because only 24% of the risk resides in the downer/high-risk population. The benefit of removing downer/high-risk cattle from human consumption has, in our view, been oversold as a public health protection measure. Strong enforcement of the FDA's feed ban, the import ban and the removal of risky material from human consumption remain our primary protections against this disease.

We acknowledge that our calculations are based on data collected in Europe, which might, in theory, differ from data collected in the United States. But there is simply no alternative to using the European data to generate estimates as analogous U.S. data do not exist. One cannot calculate the ratio of the fraction of infected downer/high-risk animals to the fraction of infected normal-appearing animals when no indigenous cases in the United States have ever been found. It is better to use available European data, where BSE experience is greatest, to make an estimate than to insist, as the USDA does, that this ratio is equal to infinity, even while acknowledging on its website that this is not true. It is noteworthy that this limitation of the surveillance programs has been raised by the Harvard Center on Risk Analysis.¹¹ In its review of the Expanded Surveillance Plan, the Center observed discretely "However, because there may be BSE-infected animals in the normal adult and normal juvenile populations, a more rigorous set of assumptions must be developed to estimate a prevalence for the entire population." In Harvard's statistical

estimates, their base case scenario used a value of eight for the ratio of the downer/high-risk animal infection rate to the rate among normal-appearing animals, based on Swiss data;¹² our analysis is based on data from all of Europe and actually leads to a more conservative analysis.*

In addition to these risk communication problems, USDA's surveillance program has been plagued by poor administration. In 2001, we conducted a study comparing the rates of BSE testing across states.¹³ Instead of finding approximately equal testing rates, we found a 600-fold difference between the states with the highest and lowest testing rates for dairy cattle (an older population and thus of particular interest), suggesting a program in disarray. (While some of this difference might be accounted for by the movement of cattle to other states for the purposes of slaughter, this is unlikely to explain the massive variations we observed, particularly when, as the USDA itself has assumed in its Expanded Surveillance Plan "most of these animals will not be moved significant distances (that is, most rendering or salvage facilities collect animals from a limited geographical area)."⁴

Furthermore, there appears to be no accepted procedure for deciding which animals to test, a point echoed in the dispute over whether the Washington BSE case was a downer animal.^{14,15} Press reports indicate that no BSE testing was conducted in the entire state of Washington in the first seven months of 2003.¹⁶ The case in Texas, where, apparently due to a decision by a USDA official not at the plant, even an animal with CNS symptoms was not tested,¹⁷ only highlights these concerns because CNS animals are the most high-risk of all cattle. Finally, some USDA inspectors have testified that the industry itself selects the cattle brains for testing.¹⁸

The Washington case has also highlighted the major deficiencies in our ability to track livestock. Only 29 of the 81 cattle in the same herd as the index BSE case could be located by the USDA investigation.¹⁹ A comprehensive, mandatory life-long tracking system must be implemented as soon as possible. However, now that downer cattle have been removed from human consumption, farmers have an incentive to bury suspect animals on the farm, without notifying the USDA. Therefore, farmers should be compensated for providing their downer animals for testing and heavy penalties should be provided for any attempts to elude testing once an on-farm surveillance system is in place.

There is much about the design of the USDA's Expanded Surveillance Program that is praiseworthy: the focus on high-risk animals, the greatly increased numbers of tests, the expansion of testing to include 20,000 normal-appearing animals and the approval of more rapid testing technologies. But, the program to date has been riddled with deficiencies in the risk communication and implementation spheres. In contrast to

* An additional problem for any BSE surveillance program is that there are certain (primarily younger) cattle that may be infected but cannot be detected by any currently available test. Fortunately, these animals are considerably less infectious. Such animals might develop symptoms of BSE or become downer animals should they live long enough. But our calculations do not address this additional problem of undetectable BSE infection, because they are based on actual tests that have been conducted in the field (detectable BSE).

what the USDA has repeatedly claimed or implied, the infected animal in Washington was probably not a downer (if it was, the claims for the effectiveness of the surveillance system would seem more credible), the previous surveillance system could not detect the one in a million risk and the Expanded Surveillance System will not detect a one in 10 million risk, the removal of downer animals from human food will have only a small protective effect on the safety of the food supply and the program has been implemented in an inconsistent fashion. If the public and potential importers of U.S. cattle and cattle products are to be reassured, it can only be on the basis of accurate scientific information, rather than the false or misleading information that has represented a significant portion of the USDA response to date.

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- ¹ Kaufman M. USDA allowed Canadian beef in despite ban. Washington Post, May 20, 2004, p. A1.
- ² Expanded "mad cow" safeguards announced to strengthen existing firewalls against BSE transmission. U.S. Department of Health and Human Services Press Release, January 26, 2004. Available at: <http://www.hhs.gov/news/press/2004pres/20040126.html>.
- ³ Federal measures to mitigate BSE risks: considerations for further action (Advance Notice of Proposed Rulemaking), July 9, 2004. Available at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04n-0264-nap0001.pdf>.
- ⁴ Bovine Spongiform Encephalopathy (BSE) Surveillance Plan. US Department of Agriculture. March 15, 2004. Available at: http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf.
- ⁵ Bovine spongiform encephalopathy: surveillance. US Department of Agriculture. Available at: <http://cofcs66.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>.
- ⁶ Health and Consumer Protection Directorate-General. Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in 2002. European Commission, June 2003. Available at: http://www.europa.eu.int/comm/food/fs/bse/testing/annual_report_2002_en.pdf.
- ⁷ National Agricultural Statistics Service. http://www.usda.gov/nass/pubs/agr03/03_ch7.pdf.
- ⁸ Kihm U, Hueston W, Matthews D, MacDiarmid SC, Heim D. Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States. Available at: http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf.
- ⁹ Ault A. Federal panel recommends more testing for mad cow. New York Times, February 14, 2004.
- ¹⁰ Donnelly CA. Bovine spongiform encephalopathy in the United States – an epidemiologist's view. New England Journal of Medicine 2004;365:539-42.
- ¹¹ Food Chemical News, March 22, 2004 (BSE News).
- ¹² Cohen J, Gray G. Comments on USDA bovine spongiform encephalopathy (BSE) surveillance plan. Harvard Center for Risk Analysis, March 12, 2004. Available at: http://www.aphis.usda.gov/lpa/issues/bse/BSE_Harvard03-12-04.pdf.
- ¹³ Public Citizen and Government Accountability Project. USDA'S Mad Cow Disease Surveillance Program: A Comparison of State Cattle-Testing Rates. Available at: <http://www.citizen.org/publications/release.cfm?ID=6783>.
- ¹⁴ McNeil DG. Man who killed mad cow has questions of his own. New York Times, February 3, 2004.
- ¹⁵ Davis T, Waxman HA. Letter to USDA Secretary Ann Veneman. Committee on Government Reform, U.S. House of Representatives, February 17, 2004.
- ¹⁶ Mitchell S. UPI exclusive: no mad cow tests in Wash. United Press International, January 15, 2004.
- ¹⁷ Kilman S. U.S. confirms a failure to use mad-cow test. Wall Street Journal, May 4, 2004, p. A6.
- ¹⁸ Carney P. Affidavit. January 14, 2004. Available at: <http://www.citizen.org/documents/paulcarneyaffidavit.pdf>.

¹⁹ Final BSE update. US Department of Agriculture, February 9, 2004. Available at: <http://www.usda.gov/Newsroom/0074.04.html>.